T2 Biosystems, Inc.
Form 10-Q
November 05, 2014
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2014

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number: 001-36571

T2 Biosystems, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**20-4827488**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
101 Hartwell Avenue Lexington, Massachusetts	**02421**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code: **(781) 457-1200**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer o
Non-accelerated filer x (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

As of October 31, 2014, the registrant had 20,041,645 shares of common stock outstanding.

Table of Contents

T2 BIOSYSTEMS, INC.

TABLE OF CONTENTS

Table of Contents

PART I.

FINANCIAL INFORMATION

Item 1. Financial Statements

T2 Biosystems, Inc.

Condensed Balance Sheets

(In thousands, except share and per share data)

(Unaudited)

	September 30, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 75,589	$ 30,198
Prepaid expenses and other current assets	1,087	195
Total current assets	76,676	30,393
Property and equipment, net	1,698	1,118
Restricted cash	340	340
Other assets	153	34
Total assets	$ 78,867	$ 31,885
Liabilities, redeemable convertible preferred stock and stockholders equity (deficit)		
Current liabilities:		
Accounts payable	$ 725	$ 943
Accrued expenses	5,580	1,319
Current portion of notes payable	290	1,759
Current portion of deferred rent	67	25
Total current liabilities	6,662	4,046
Notes payable, net of current portion	10,733	3,299
Deferred rent, net of current portion	18	45
Warrants to purchase redeemable securities		1,225
Other liabilities	24	
Commitments and contingencies		
Redeemable convertible preferred stock		112,813
Stockholders equity (deficit):		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued		
Common stock, $0.001 par value; 200,000,000 and 28,254,907 shares authorized at September 30, 2014 and December 31, 2013, respectively; 20,040,604 and 1,411,986 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	20	1
Additional paid-in capital	155,929	

Accumulated deficit	(94,519)	(89,544)
Total stockholders equity (deficit)	61,430	(89,543)
Total liabilities, redeemable convertible preferred stock and stockholders equity (deficit)	$ 78,867	$ 31,885

Table of Contents

T2 Biosystems, Inc.

Condensed Statements of Operations and Comprehensive Loss

(In thousands, except share and per share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Research and grant revenue	$	$ 91	$	$ 211
Operating expenses:				
Research and development	4,803	3,358	14,572	10,646
Selling, general and administrative	2,984	1,275	7,271	3,618
Total operating expenses	7,787	4,633	21,843	14,264
Loss from operations	(7,787)	(4,542)	(21,843)	(14,053)
Interest expense, net	(304)	(100)	(471)	(310)
Other income (expense), net			(1)	125
Net loss	$ (8,091)	$ (4,642)	$ (22,315)	$ (14,238)
Comprehensive loss	$ (8,091)	$ (4,642)	$ (22,315)	$ (14,238)
Reconciliation of net loss to net loss applicable to common stockholders:				
Net loss	$ (8,091)	$ (4,642)	$ (22,315)	$ (14,238)
Accretion of redeemable convertible preferred stock to redemption value	$ (758)	$ (1,911)	$ (4,570)	$ (4,998)
Net loss applicable to common stockholders	$ (8,849)	$ (6,553)	$ (26,885)	$ (19,236)
Net loss per share applicable to common stockholders basic and diluted	$ (0.71)	$ (4.69)	$ (5.25)	$ (13.82)
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders basic and diluted	12,379,337	1,398,425	5,120,977	1,392,110

Table of Contents

T2 Biosystems, Inc.

Condensed Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2014	**2013**
Operating activities		
Net loss	$ (22,315)	$ (14,238)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	459	438
Stock-based compensation expense	1,057	340
Noncash interest expense	102	33
Change in fair value of warrants	1	(110)
Loss on disposal of asset		6
Deferred rent	15	(4)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(901)	(97)
Accounts payable	(227)	(49)
Accrued expenses and other liabilities	2,110	206
Net cash used in operating activities	(19,699)	(13,475)
Investing activities		
Purchases of property and equipment	(1,039)	(450)
Decrease in restricted cash		80
Net cash used in investing activities	(1,039)	(370)
Financing activities		
Proceeds from issuance of common stock in initial public offering, net of offering costs	60,145	
Proceeds from issuance of redeemable convertible preferred stock, net		39,768
Proceeds from issuance of common stock and stock option exercises	150	38
Proceeds from notes payable, net of deferred financing costs	9,800	
Repayment of notes payable	(3,966)	(451)
Net cash provided by financing activities	66,129	39,355
Net increase in cash and cash equivalents	45,391	25,510
Cash and cash equivalents at beginning of period	30,198	9,709
Cash and cash equivalents at end of period	$ 75,589	$ 35,219
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 294	$ 251
Supplemental disclosures of noncash investing and financing activities		
Accretion of Series A-1, A-2, B, C, D and E redeemable convertible preferred stock to redemption value	$ 4,570	$ 4,998
Deferred financing costs incurred but unpaid at period end	$ 80	$
Initial public offering costs incurred but unpaid at period end	$ 2,104	$
Conversion of redeemable convertible preferred stock to common stock	$ 117,383	$
Conversion of preferred stock warrants to common stock	$ 1,226	$

Table of Contents

T2 Biosystems, Inc.

Notes to Condensed Financial Statements

(Unaudited)

1. Nature of Business

T2 Biosystems, Inc. (the Company) was incorporated on April 27, 2006 as a Delaware corporation with operations based in Lexington, Massachusetts. The Company is an *in vitro* diagnostic company that has developed an innovative and proprietary platform that enables rapid, sensitive and simple direct detection of pathogens, biomarkers and other abnormalities across a variety of unpurified patient sample types. The Company is using its T2 Magnetic Resonance platform (T2MR) to develop a broad set of applications aimed at reducing mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier. The Company s initial development efforts target sepsis and hemostasis, areas of significant unmet medical need in which existing therapies could be more effective with improved diagnostics. On September 22, 2014, the Company received market authorization from the U.S. Food and Drug Administration (FDA) for its first two products, the T2Dx diagnostic instrument (T2Dx) and T2Candida panel (T2Candida).

Since inception, the Company has devoted substantially all of its efforts to research and development, business planning, recruiting management and technical staff, acquiring operating assets, raising capital, and, most recently, commercialization of its products.

Liquidity

At September 30, 2014 the Company has generated an accumulated deficit of $94.5 million (see Note 6 for additional disclosure of the effects of the initial public offering on accumulated deficit). The future success of the Company is dependent on its ability to successfully commercialize its newly authorized products, obtain regulatory clearance for and successfully launch its future product candidates and ultimately attain profitable operations, and obtain additional capital, if needed. Historically, the Company has funded its operations primarily through private placements of its redeemable convertible preferred stock and through debt financing arrangements. On August 12, 2014, the Company completed its initial public offering (IPO) whereby the Company sold 5,980,000 shares of its common stock for net proceeds of approximately $58.0 million (Note 6). As a result of the completion of the IPO and additional liquidity of up to $30.0 million available from the loan and security agreement that closed on July 11, 2014 (Note 5), management believes that its cash resources will be sufficient to allow the Company to fund its current operating plan through at least the next 18 months.

The Company is subject to a number of risks similar to other newly commercial life science companies, including, but not limited to commercially launching the Company s products, development and market acceptance of the Company s future product candidates, development by its competitors of new technological innovations, protection of proprietary technology, and raising additional capital.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company s financial statements have been prepared in conformity with generally accepted accounting principles in the United States of America (GAAP). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASU) of the Financial Accounting Standards Board (FASB).

Table of Contents

Unaudited Interim Financial Information

Certain information and footnote disclosures normally included in the Company s annual financial statement have been condensed or omitted. Accordingly, these interim condensed financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company s Registration Statement on Form S-1 filed on August 6, 2014, which includes the annual financial statements for the fiscal year ended December 31, 2013.

The accompanying interim balance sheet as of September 30, 2014, the statements of operations and comprehensive loss for the three and nine months ended September 30, 2014 and 2013, the statements of cash flows for the nine months ended September 30, 2014 and 2013 and the related financial data and other information disclosed in these notes are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements, and, in the opinion of management, reflect all adjustments, consisting of normal recurring adjustments, necessary for the fair presentation of the Company s financial position as of September 30, 2014, and the results of its operations and its cash flows for the three and nine months ended September 30, 2014 and 2013. The results for the three and nine months ended September 30, 2014 are not necessarily indicative of the results to be expected for the year ending December 31, 2014, any other interim periods, or any future year or period.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company s chief operating decision maker is the Chief Executive Officer. The Company views its operations and manages its business in one operating segment, which is the business of developing and launching commercially its diagnostic products aimed at reducing mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier.

Inventory

Inventory is stated at the lower of cost or market with cost determined under the first-in, first-out basis.

The Company capitalizes inventories in preparation for sales of products when the related product candidates are considered to have a high likelihood of regulatory clearance and the related costs are expected to be recoverable through sales of the inventories. In addition, the Company capitalizes inventories related to the manufacture of instruments that have a high likelihood of regulatory clearance and will be retained as the Company s assets, upon determination that the instrument has alternative future uses. In determining whether or not to capitalize such inventories, the Company evaluates, among other factors, information regarding the product candidate s status of regulatory submissions and communications with regulatory authorities, the outlook for commercial sales and alternative future uses of the product candidate, including commercial sale.

Costs associated with development products prior to satisfying the inventory capitalization criteria are charged to research and development expense as incurred.

The Company began capitalizing inventories upon receipt of market authorization from the FDA for its first two products. Inventory meeting the capitalization criteria as of September 30, 2014 is not significant to the financial statements and is recorded as a component of prepaid expenses and other current assets in the Condensed Balance Sheets.

Reverse Stock Split

The Company effected a 1-for-1.7 reverse stock split of its issued and outstanding common stock on July 25, 2014. All share and per share amounts related to issued and outstanding common stock, outstanding options and warrants exercisable for common stock included in these financial statements and notes to the financial statements and have been retroactively adjusted for all periods presented to reflect the reverse stock split, including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital. The shares authorized, issued and outstanding of the Company s redeemable convertible preferred stock are not impacted by the reverse stock split and have not been adjusted. However, the conversion ratios of the Company s redeemable convertible preferred stock for the purpose of determining the common stock issued upon conversion (Note 6) have been adjusted to reflect the reverse stock split.

Table of Contents

Net Loss Per Share

Basic net loss per share is calculated by dividing net loss applicable to common stockholders, which is net loss plus accretion of redeemable convertible preferred stock to redemption value in the period, by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting the weighted-average number of shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method for outstanding stock options and warrants. For purposes of the diluted net loss per share calculation, redeemable convertible preferred stock, warrants to purchase redeemable convertible preferred stock and stock options are considered to be common stock equivalents, but have been excluded from the calculation of diluted net loss per share, as their effect, including the related impact to the numerator of the fair value adjustment of the warrant and the impact to the denominator of the warrant shares, would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share applicable to common stockholders were the same for all periods presented.

Guarantees

From time to time, the Company enters into indemnification agreements in the ordinary course of business, including, but not limited to, indemnification agreements with directors and officers, within its lease agreements for office, laboratory and manufacturing space, and with certain suppliers and business partners. As of September 30, 2014 and December 31, 2013, the Company had not experienced any material losses related to these indemnification obligations, and no material claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

Recently Issued or Adopted Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In June 2014, the FASB issued amended guidance, ASU No 2014-09, *Revenue from Contracts with Customers*, which is applicable to revenue recognition that will be effective for the Company for the year ended December 31, 2017. The new guidance must be adopted using either a full retrospective approach for all periods presented or a modified retrospective approach. Early adoption is not permitted. The new guidance applies a more principles-based approach to revenue recognition. The Company is evaluating the new guidance and the expected effect on the Company s condensed financial statements.

In June 2014, the FASB issued ASU 2014-10, *Development Stage Entities (Topic 915)* (ASU 2014-10), which removes the definition of a development stage entity from the ASC, thereby removing the financial reporting distinction between development stage entities and other reporting entities. Accordingly, ASU 2014-10 eliminates the requirements for development stage entities to (1) present inception-to-date information in the statements of operations, cash flows and shareholder equity, (2) label financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. ASU 2014-10 is effective for public

business entities for annual periods beginning after December 15, 2014, and interim reporting periods beginning after December 15, 2015, with early adoption permitted. The Company has adopted the provisions of ASU 2014-10 in the June 30, 2014 Quarterly Report on Form 10-Q.

Table of Contents

3. Fair Value Measurements

The Company measures the following financial assets and liabilities at fair value on a recurring basis. In general, fair values determined by Level 1 inputs utilize observable inputs such as quoted prices in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are either directly or indirectly observable, such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points in which there is little or no market data, which require the Company to develop its own assumptions for the asset or liability. The Company has not changed the manner in which it values the liability for warrants to purchase redeemable securities, which is measured at fair value using Level 3 inputs. There were no transfers between levels of the fair value hierarchy during any of the periods presented. The following tables set forth the Company s financial assets and liabilities carried at fair value categorized using the lowest level of input applicable to each financial instrument as of September 30, 2014 and December 31, 2013 (in thousands):

	Balance at September 30, 2014	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash	$ 65,119	$ 65,119	$	$
Money market funds	10,470	10,470		
Restricted cash	340	340		
	$ 75,929	$ 75,929	$	$
Liabilities:				
Warrants to purchase redeemable securities	$	$	$	$
	$	$	$	$

	Balance at December 31, 2013	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash	$ 2,631	$ 2,631	$	$
Money market funds	27,567	27,567		
Restricted cash	340	340		
	$ 30,538	$ 30,538	$	$
Liabilities:				
Warrants to purchase redeemable securities	$ 1,225	$	$	$ 1,225
	$ 1,225	$	$	$ 1,225

Table of Contents

The fair value of the Company s preferred stock warrant liability represents a recurring measurement that is classified within Level 3 of the fair value hierarchy, wherein fair value is estimated using significant unobservable inputs. The Company determined the fair value of the warrants to purchase redeemable convertible preferred stock based on input from management and the board of directors, which utilized an independent valuation of the Company s enterprise value, determined utilizing an analytical valuation model, which as of August 6, 2014, the date just prior to the net exercise of the warrants into commons stock, was a hybrid approach based on an Option Pricing Model (OPM) and the Probability Weighted Expected Return Method (PWERM). Each valuation methodology includes estimates and assumptions that require the Company s judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions affecting the *in vitro* diagnostics industry sector, the prices at which the Company sold shares of preferred stock, the superior rights and preferences of securities at the time and the likelihood of achieving a liquidity event, such as an initial public offering or a sale of the Company. Any changes in the assumptions used in the valuation could materially affect the financial results of the Company. The following table sets forth a summary of changes in the fair value of the Company s preferred stock warrant liability (in thousands):

	Nine Months Ended September 30, 2014
Beginning balance	$ 1,225
Additional warrants issued	
Change in fair value, recorded as a component of other income (expense)	1
Net exercise of warrants into common stock	(1,226)
Ending balance	$

For certain financial instruments, including accounts payable and accrued expenses, the carrying amounts approximate their fair values as of September 30, 2014 and December 31, 2013 because of their short-term nature. At September 30, 2014 and December 31, 2013, the carrying value of the Company s debt approximated fair value, which was determined using Level 3 inputs, including a quoted interest rate.

4. Supplemental Balance Sheet Information

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2014	December 31, 2013
Accrued professional services	$ 3,038	$ 101
Accrued payroll and compensation	1,287	496
Accrued research and development expenses	257	422
Other accrued expenses	998	300
Total accrued expenses	$ 5,580	$ 1,319

Table of Contents

5. Debt

On July 11, 2014, the Company entered into a loan and security agreement (the Note Agreement) with two lenders to borrow up to $30.0 million for operations. The Note Agreement allows the Company to borrow amounts in two tranches, up to $20.0 million (drawn in amounts not less than $10.0 million upon closing and the remainder drawn in amounts not less than $5.0 million draws) by December 31, 2014 for tranche A and up to $10.0 million by June 30, 2015 for tranche B. Under the Note Agreement, borrowings under tranche B are only available to the Company if both of the following conditions are met by June 30, 2015: (a) the Company receives Section 510(k) clearance from the FDA on the Company s T2Dx and T2Candida products and (b) the Company completes a public or private stock offering, equity raise or strategic partner arrangement resulting in the receipt of at least $30.0 million in net proceeds by the Company. As the Company received FDA approval in September 2014 and the Company closed its initial public offering in August 2014, the borrowings under tranche B are now available as both of the required conditions have been met.

Through September 30, 2014, the Company received proceeds of $9.8 million under tranche A, net of deferred financing costs. To date, the Company has not drawn the remaining tranche A and tranche B available borrowings.

The amounts borrowed under the Note Agreement are collateralized by substantially all of the assets of the Company and bear interest at the one-month LIBOR plus 7.05%, which was 7.21% on September 30, 2014. The Company will pay interest only payments on the amounts borrowed under the Note Agreement through July 31, 2016. After the interest only period, the Company will repay the amounts borrowed in equal monthly installments until the maturity date of July 1, 2019. The Note Agreement requires payment of a final fee of 4.75% of the aggregate original principal of amounts borrowed, which the Company is accruing over the term of the Note Agreement. In addition, amounts borrowed may be prepaid at the option of the Company in denominations of not less than $1,000,000, and any amounts prepaid are subject to a prepayment premium of 1.5% if prepaid prior to the first anniversary of the borrowing date, 1.0% if prepaid prior to the second anniversary of the borrowing date and after the first anniversary of the borrowing date, and 0.5% if prepaid prior to the maturity date and after the second anniversary of the borrowing date. The effective interest rate for the Note Agreement, including final fee interest and non-cash interest, is 9.44%.

The Note Agreement does not include any financial covenants, but does contain a subjective acceleration clause whereby upon an event of default, which includes a material adverse change in the business, operations, or conditions (financial or otherwise) of the Company or a material impairment of the prospect of repayment of any portion of the obligations, there can be an immediate acceleration of the borrowings under the Note Agreement. The Company concluded that a material adverse change has not occurred and is unlikely to occur and therefore the debt has been classified as a long-term liability.

The Company assessed all terms and features of the Note Agreement in order to identify any potential embedded features that would require bifurcation or any beneficial conversion features. As part of this analysis, the Company assessed the economic characteristics and risks of the Note Agreement, including put and call features. The Company determined that all features of the Note Agreement are clearly and closely associated with a debt host and do not require bifurcation as a derivative liability, or the fair value of the feature is immaterial. The Company will continue to reassess the features to determine if they require separate accounting on a quarterly basis.

In connection with the closing of the Note Agreement, the Company repaid all amounts outstanding under previously existing borrowing arrangement with a lender, totaling approximately $2.9 million, as of July 11, 2014.

9

Table of Contents

6. Stockholders Equity (Deficit)

Initial Public Offering

On August 12, 2014, the Company completed its IPO, whereby the Company sold 5,980,000 shares of its common stock (inclusive of 780,000 shares of common stock sold by the Company pursuant to the full exercise of an overallotment option granted to the underwriters in connection with the offering) at a price of $11.00 per share. The shares began trading on the Nasdaq Global Market on August 7, 2014. The net proceeds received by the Company from the offering were approximately $58.0 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company. At September 30, 2014, offering expenses related to the IPO totaling $2.1 million were incurred, but unpaid. Upon the closing of the IPO, all outstanding shares of redeemable convertible preferred stock converted into 12,516,298 shares of common stock and warrants exercisable for redeemable convertible preferred stock net exercised into 68,700 shares of common stock, resulting in a reclassification of the related liability for warrants to purchase redeemable convertible preferred stock to common stock (par value) and additional paid-in capital. On the conversion date, the redeemable convertible preferred stock had a balance of $117.4 million, which was recorded in temporary equity. Upon conversion into common stock, this balance was reclassified as stockholders equity, reducing accumulated deficit by $21.0 million, with the residual amount of $96.4 million recorded as common stock (par value) and additional paid-in capital. The amount recorded as a reduction in accumulated deficit reflects the value of redeemable convertible preferred stock dividends and issuance costs accreted through the conversion date. In addition, the following other items became effective with the closing of the IPO:

(i) On July 25, 2014, the Company filed an amendment to the Certificate of Incorporation to effect the aforementioned stock split, increase the authorized number of shares of common stock from 29,880,899 to 60,000,000, eliminate anti-dilution protection for the preferred stock in the connection with the issuance of common stock as part of the IPO and amend the mandatory conversion provision to remove the minimum price per share and minimum gross proceeds conditions in connection with the IPO. Upon closing of the IPO, the number of authorized shares of common stock of the Company increased to 200,000,000 and the Company is authorized to issue up to 10,000,000 shares of preferred stock.

(ii) On July 19, 2014, the Company s board of directors adopted and, on July 21, 2014, the Company s stockholders approved, the 2014 Incentive Award Plan (2014 Plan), which became effective on August 6, 2014. The 2014 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, restricted stock units, stock appreciation rights and other stock-based awards. The Company s employees, officers, directors, consultants and advisors are eligible to receive awards under the 2014 Plan.

(iii) On July 19, 2014, the Company s board of directors adopted and, on July 21, 2014, the Company s stockholders approved, the 2014 Employee Stock Purchase Plan (2014 ESPP), which became effective on August 6, 2014. The 2014 ESPP will enable eligible employees to purchase shares of the Company s common stock at a discount.

Stock-Based Compensation

2006 Stock Incentive Plan

The Company s 2006 Stock Option Plan (the 2006 Plan) was established for granting stock incentive awards to directors, officers, employees and consultants to the Company. Upon closing of the Company s IPO in August 2014, the Company ceased granting stock incentive awards under the 2006 Plan. The 2006 Plan provided for the grant of incentive and non-qualified stock options and restricted stock grants as determined by the Board of Directors. Under the 2006 Plan, stock options were generally granted with exercise prices equal to or greater than the fair value of the common stock as determined by the board of directors, expired no later than 10 years from the date of grant, and vest over various periods not exceeding 4 years.

2014 Stock Incentive Plan

The Company s 2014 Plan provides for the issuance of shares of common stock in the form of stock options, awards of restricted stock, awards of restricted stock unit awards, performance awards, dividend equivalent awards, stock payment awards and stock appreciation rights to directors, officers, employees and consultants of the Company. Since the establishment of the 2014 Plan, the Company has only granted stock options. Generally, stock options are granted with exercise prices equal to or greater than the fair value of the common stock on the date of grant, expire no later than 10 years from the date of grant, and vest over various periods not exceeding 4 years.

Table of Contents

The number of shares reserved for future issuance under the 2014 Plan is the sum of (1) 823,529, (2) any shares that were granted under the 2006 Plan which are forfeited, lapse unexercised or are settled in cash subsequent to the effective date of the 2014 Plan and (3) an annual increase on the first day of each calendar year beginning January 1, 2015 and ending on January 1, 2024, equal to the lesser of (A) 823,529 shares, (B) 4% of the shares outstanding (on an as-converted basis) on the final day of the immediately preceding calendar year and (C) such smaller number of shares determined by the Board of Directors. As of September 30, 2014 there were 667,717 shares available for future grant under the Plan.

Stock Options

During the nine months ended September 30, 2014, the Company granted options with an aggregate fair value of $3,843,000, which are being amortized into compensation expense over the vesting period of the options as the services are being provided. The following is a summary of option activity under the Plans:

	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value (In thousands)
Outstanding at December 31, 2013	2,265,973	$ 2.53	8.23	11,510
Granted	672,972	11.98		
Exercised	(63,602)	2.35		
Cancelled	(84,026)	2.44		
Outstanding at September 30, 2014	2,791,317	4.82	8.04	37,039
Exercisable at September 30, 2014	1,281,272	2.24	6.65	20,303
Vested or expected to vest at September 30, 2014	2,433,313	4.59	7.89	32,850

The total fair values of stock options that vested during the nine months ended September 30, 2014 was $812,000.

The weighted-average fair values of options granted in the nine-month periods ended September 30, 2014 and 2013 were $5.71 per share and $1.85 per share, respectively, and were calculated using the following estimated assumptions:

	Nine Months Ended September 30,	
	2014	2013
Weighted-average risk-free interest rate	1.85% - 2.04%	1.02% - 1.78%
Expected dividend yield	0.00%	0.00%
Expected volatility	60% - 62%	63% - 64%
Expected terms	5.75 - 6.08 years	5.77 - 6.08 years

Table of Contents

Employee Stock Purchase Plan

The 2014 ESPP provides initially for the granting of up to 220,588 shares of the Company s common stock to eligible employees. The 2014 ESPP plan period is semi-annual and allows participants to purchase the Company s common stock at 85% of the lower of (i) the market value per share of common stock on the first day of the offering period or (ii) the market value per share of the common stock on the purchase date. Each participant can purchase up to a maximum of $25,000 per year in fair market value, as determined by the market value per share of common stock at the beginning of the offering period. The first plan period began on August 7, 2014. Stock-based compensation expense from the 2014 ESPP for the three- and nine-months ended September 30, 2014 was $39,000.

Stock-Based Compensation Expense

The following table summarizes the stock-based compensation expense for stock options granted to employees and the and nonemployees, as well as stock-compensation expense for the 2014 ESPP that was recorded in the Company s results of operations for the three and nine months ended September 30, 2014 and 2013 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Research and development	$ 127	$ 37	$ 250	$ 117
Selling, general and administrative	425	76	807	223
Total stock-based compensation expense	$ 552	$ 113	$ 1,057	$ 340

As of September 30, 2014, there was $3,889,000 of total unrecognized compensation cost related to non-vested stock options granted under the 2006 and 2014 Plans. Total unrecognized compensation cost will be adjusted for future changes in the estimated forfeiture rate. The Company expects to recognize that cost over a remaining weighted-average period of 3.2 years as of September 30, 2014.

7. Net Loss Per Share

The following shares were excluded from the calculation of diluted net loss per share applicable to common stockholders, prior to the application of the treasury stock method, because their effect would have been anti-dilutive for the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Redeemable convertible preferred stock		12,516,298		12,516,298
	2,791,317	2,033,450	2,791,317	2,033,450

Options to purchase common shares				
Warrants to purchase redeemable convertible preferred stock		147,484		147,484
Total	2,791,317	14,697,232	2,791,317	14,697,232

Table of Contents

8. Commitments and Contingencies

Lease Amendment

On July 11, 2014, the Company entered into a lease amendment to expand facilities at the Company s headquarters in Lexington, MA. The term of the lease amendment ends concurrently with the original lease entered into in August 2010 and will increase the monthly base rent by approximately $39,000 per month through December 2015. The Company retains the option to extend the lease for one additional term of two years.

Table of Contents

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

This Quarterly Report on Form 10-Q contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial position, business strategy, prospective products and product candidates, their expected performance and impact on healthcare costs, marketing authorization from the U.S. Food and Drug Administration, or FDA, regulatory clearance, reimbursement for our product candidates, research and development costs, timing of regulatory filings, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as may, will, should, expect, plan, anticipate, could, intend, target, project, contemplate, believe, estimate, predict, potential or continue or the negative of these terms or other similar expressions. The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of risks, uncertainties and assumptions described under the sections in this prospectus entitled Item 1A. Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this Quarterly Report on Form 10-Q. These forward looking statements are subject to numerous risks, including, without limitation, the following:

- *our expectation to incur losses in the future;*
- *our ability to obtain marketing authorization from the FDA or regulatory clearance for new product candidates in the United States or any other jurisdiction;*
- *the market acceptance of our T2MR technology;*
- *our ability to timely and successfully develop and commercialize our existing products and future product candidates;*
- *the length of our anticipated sales cycle;*

- *our ability to gain the support of leading hospitals and key thought leaders and publish the results of our clinical trials in peer-reviewed journals;*

- *our future capital needs and our need to raise additional funds;*

- *the performance of our diagnostics;*

- *our ability to successfully manage our growth;*

- *our ability to compete in the highly competitive diagnostics market;*

- *our ability to protect and enforce our intellectual property rights, including our trade secret-protected proprietary rights in T2MR; and*

- *federal, state, and foreign regulatory requirements, including FDA regulation of our product candidates.*

Table of Contents

These forward-looking statements represent our estimates and assumptions only as of the date of this Quarterly Report on Form 10-Q. Unless required by U.S. federal securities laws, we do not intend to update any of these forward-looking statements to reflect circumstances or events that occur after the statement is made or to conform these statements to actual results. The following discussion should be read in conjunction with the financial statements and notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under Risk Factors in our Registration Statement on Form S-1 filed on August 6, 2014, which includes financial statements for the year ended December 31, 2013, as supplemented or amended from time to time under Item 1A. Risk Factors in our Quarterly Reports on Form 10-Q, and elsewhere in this Quarterly Report on Form 10-Q.

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the Item 1A. Risk Factors section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Table of Contents

Business Overview

We are an *in vitro* diagnostics company that has developed an innovative and proprietary technology platform that offers a rapid, sensitive and simple alternative to existing diagnostic methodologies. We are using our T2 Magnetic Resonance platform, or T2MR, to develop a broad set of applications aimed at lowering mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier. Our initial development efforts utilizing T2MR target sepsis and hemostasis, which are areas of significant unmet medical need where existing therapies could be more effective with improved diagnostics. On September 22, 2014, we received market authorization from the U.S. Food and Drug Administration for our first two products, the T2Dx diagnostic instrument (T2Dx) and the T2Candida Panel (T2Candida), for the direct detection of *Candida* species in human whole blood specimens and independent of blood culture from patients with symptoms of, or medical conditions predisposing the patient to, invasive fungal infections. We have begun a launch of the T2Dx and T2Candida with select hospitals in the United States and we are building a direct sales force that will initially target the top 450 hospitals in the United States. In addition, we expect to initiate clinical trials for our bacterial sepsis and hemostasis product candidates in the second half of 2015 and the first half of 2016, respectively, and are targeting to commercialize these product candidates in 2017. We believe our combined initial annual addressable market opportunity for sepsis and hemostasis is over $3 billion in the United States alone, when the market opportunity for T2Candida, T2Bacteria Panel and our initial hemostasis diagnostic panel is combined.

We have never been profitable and have incurred net losses in each year since inception. Our accumulated deficit at September 30, 2014 was $94.5 million. Substantially all our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. Having recently obtained authorization from the FDA to market the T2Dx and T2Candida, we now expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. In addition, we expect that our expenses will increase substantially as we continue the research and development of our other products candidates and maintain, expand and protect our intellectual property portfolio. Accordingly, we may seek to fund our operations through public or private equity or debt financings or other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop and commercialize the T2Dx and T2Candida and our other product candidates.

Historically, the Company has funded its operations primarily through private placements of its redeemable convertible preferred stock and through debt financing arrangements. On August 12, 2014, the Company completed its IPO whereby the Company sold 5,980,000 shares of its common stock for net proceeds of approximately $58.0 million. As a result of the completion of the IPO and additional liquidity of up to $30.0 million obtained from the loan and security agreement that closed on July 11, 2014, management believes that its cash resources will be sufficient to allow the Company to fund its current operating plan through at least the next 18 months.

Table of Contents

Our Commercial Products and the Unmet Clinical Need

Our initial FDA-authorized products, the T2Dx and T2Candida utilize T2MR to detect species-specific *Candida* directly from whole blood in 3-5 hours versus the 2-5 days required by blood culture-based diagnostics. The T2Candida runs on the T2Dx and provides high sensitivity with a limit of detection as low as 1 CFU/mL, even in the presence of antimicrobial therapy.

Our T2Candida Panel

Our direcT2 pivotal clinical trial was designed to evaluate the sensitivity and specificity of the T2Candida on the T2Dx. The direcT2 trial consisted of two patient arms: a prospective arm with 1,501 samples from patients with a possible infection and a seeded arm with 300 samples, also obtained from patients with a possible infection. T2Candida and T2Dx demonstrated a sensitivity of 91.1 percent and a specificity of 99.4 percent. In addition, the speed to a species-specific positive result with T2Candida was 4.4 hours versus 129 hours with blood culture. A negative result from T2Candida was obtained in just 4.2 hours versus 120 hours with blood culture.

Candida is the fourth leading hospital acquired and the most lethal form of common bloodstream infection that cause sepsis, with an average mortality rate of approximately 40%. This high mortality rate is largely due to the elapsed time from *Candida* infection to positive diagnosis and treatment. According to a study published in Antimicrobial Agents and Chemotherapy, the *Candida* mortality rate can be reduced to 11% with the initiation of targeted therapy within 12 hours of presentation of symptoms. Additionally, a typical patient with a *Candida* infection averages 40 days in the hospital, including nine days in intensive care, resulting in an average cost per hospital stay of more than $130,000 per patient. In a study published in the American Journal of Respiratory and Critical Care Medicine, providing targeted antifungal therapy within 24 hours of the presentation of symptoms decreased the length of hospital stay by approximately 10 days and decreased the average cost of care by approximately $30,000 per patient.

Additionally, the speed to result of the T2Candida, run on the T2Dx, can help reduce the empiric overuse of ineffective, or even unnecessary, antimicrobial therapy. This inappropriate therapy is driving force behind the spread of antimicrobial-resistant pathogens, which the U.S. Centers for Disease Control and Prevention, or the CDC, recently called one of our most serious health threats.

Our T2Dx Instrument

Our FDA-authorized T2Dx is an easy-to-use, fully-automated, benchtop instrument utilizing T2MR for use in hospitals and labs for a broad range of diagnostic tests. To operate the system, a patient sample tube is snapped onto a disposable test cartridge, which is pre-loaded with all necessary reagents. The cartridge is then inserted into T2Dx, which automatically processes the sample and then delivers a diagnostic test result. Test results are displayed on screen or directly through the lab information system (LIS).

By utilizing our proprietary T2MR for direct detection, the T2Dx eliminates the need for sample purification and analyte extraction, which are necessary for other optical-detection devices. Eliminating these sample processing steps increases diagnostic sensitivity and accuracy, enables a broad menu of tests to be run on a single platform, and greatly reduces the complexity of the consumables. The T2Dx incorporates a simple user

interface and is designed to efficiently process up to seven specimens simultaneously.

Table of Contents

Our T2MR Platform

T2MR is a miniaturized, magnetic resonance-based approach that measures how water molecules react in the presence of magnetic fields. For molecular and immunodiagnostics targets, T2MR introduces nanoparticles to the sample that are coated with target-specific binding agents. If the target is present, the nanoparticles bind to and cluster around it, disrupting the surrounding water molecules and altering the magnetic resonance signal.

For hemostasis measurements, T2MR is highly sensitive to changes in viscosity in a blood sample (such as clot formation, stabilization or dissipation), which alter the magnetic resonance signal and enable identification of clinically relevant hemostasis changes.

We believe T2MR is the first technology with the ability to detect directly from a clinical sample of whole blood, plasma, serum, saliva, sputum or urine, saving time and potentially improving sensitivity by eliminating the need for purification or the extraction of target pathogens. T2MR has been proven to detect cellular targets at limits of detection as low as one colony-forming unit per milliliter (CFU/mL). More than 100 studies published in peer reviewed journals have featured T2MR in a breadth of applications.

Table of Contents

Financial Overview

Revenue

To date, we have generated revenue primarily from research and development agreements and government grants and have not generated any revenue from the sale of products. Revenue earned from activities performed pursuant to research and development agreements and grants is reported as revenue using the proportional performance method as the work is completed, and the related costs are expensed as incurred as research and development expense.

Product revenue will be derived from the sale of our instruments and related consumable diagnostic tests. In the majority of cases, we expect to place instruments in hospitals at minimal or no direct cost to customers in exchange for longer-term agreements and minimum commitments for the purchase of our consumable diagnostic tests. Under this business model, we believe we will recover the cost of placing our instruments in hospitals through the margins realized from our consumable diagnostic tests. Our consumable diagnostic tests can only be used with our instruments, and accordingly, as the installed base of our instruments grows, we expect the following to occur:

- recurring revenue from our consumable diagnostic tests will increase and become subject to less period-to-period fluctuation;
- consumable revenue will become an increasingly predictable and important contributor to our total revenue; and
- we will gain economies of scale through the growth in our sales, resulting in improving gross margins and operating margins.

Revenue from consumables is expected to be based on the volume of tests sold and the price of each consumable unit.

We plan to continue to expand our capacity to support our growth, which will result in higher cost of revenue in absolute dollars. However, we expect cost of revenue, as a percentage of revenue, to decline as revenue grows.

Research and development expenses

Our research and development expenses consist primarily of costs incurred for development of our technology and product candidates, technology improvements and enhancements, clinical trials to evaluate the clinical utility of our product candidates, and laboratory development and expansion, and include salaries and benefits, including stock-based compensation, research-related facility and overhead costs, laboratory

supplies, equipment and contract services. We expense all research and development costs as incurred.

We expect that our overall research and development expenses will continue to increase in absolute dollars. We have committed, and expect to commit, significant resources developing additional product candidates, improving product performance and reliability, conducting ongoing and new clinical trials and expanding our laboratory capabilities.

Table of Contents

Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of costs for our sales and marketing, finance, human resources, business development and general management functions, as well as professional services, such as legal, consulting and accounting services. We expect selling, general and administrative expenses to increase in future periods as we commercialize products and future product candidates that receive marketing authorization or regulatory clearance and as our needs for sales, marketing and administrative personnel grow. Other selling, general and administrative expenses include facility-related costs, fees and expenses associated with obtaining and maintaining patents, clinical and economic studies and publications, marketing expenses, and travel expenses. We also anticipate increased expenses related to audit, legal, regulatory and tax-related services associated with being a public company. We expense all selling, general and administrative expenses as incurred.

Interest expense, net

Interest expense, net, consists primarily of interest expense on our notes payable and the amortization of deferred financing costs, partially offset by interest earned on our cash and cash equivalents.

Other income (expense), net

Other income (expense), net, consists primarily of the gain or loss associated with the change in the fair value of our liability for warrants to purchase redeemable securities.

Critical Accounting Policies and Use of Estimates

The items that we disclosed as our critical accounting policies and estimates in Management s Discussion and Analysis of Financial Condition and Results of Operations in our Registration Statement Filing on Form S-1 filed with the Securities and Exchange Commission on August 12, 2014 remain unchanged, except for the following. For a description of those critical accounting policies, please refer to our Registration Statement on Form S-1 filing.

Inventory

Inventory is stated at the lower of cost or market with cost determined under the first-in, first-out basis.

The Company capitalizes inventories in preparation for sales of products when the related product candidates are considered to have a high likelihood of regulatory clearance and the related costs are expected to be recoverable through sales of the inventories. In addition, the Company capitalizes inventories related to the manufacture of instruments that have a high likelihood of regulatory clearance and will be retained as the Company s assets, upon determination that the instrument has alternative future uses. In determining whether or not to capitalize such inventories, the Company evaluates, among other factors, information regarding the product candidate s status of regulatory submissions and communications with regulatory authorities, the outlook for commercial sales and alternative future uses of the product candidate, including commercial sale.

Costs associated with development products prior to satisfying the inventory capitalization criteria are charged to research and development expense as incurred.

Table of Contents

Results of Operations for the Three Months Ended September 30, 2014 and September 30, 2013

	Three Months Ended September 30,		
	2014	2013	Change
		(in thousands)	
Research and grant revenue	$	$ 91	$ (91)
Operating expenses:			
Research and development	4,803	3,358	1,445
Selling, general and administrative	2,984	1,275	1,709
Total operating expenses	7,787	4,633	3,154
Loss from operations	(7,787)	(4,542)	(3,245)
Interest expense, net	(304)	(100)	(204)
Other income (expense), net			
Net loss	$ (8,091)	$ (4,642)	$ (3,449)

Research and development expenses

Research and development expenses were $4.8 million for the three months ended September 30, 2014, compared to $3.4 million for the three months ended September 30, 2013, an increase of $1.4 million. The increase was primarily due to increased payroll and payroll related expenses of $0.9 million, including $0.1 million of stock compensation expense, as we increased full-time and temporary headcount, increased licensing fees of $0.3 million as a result of milestone payments that became due pursuant to our license arrangement with Massachusetts General Hospital (MGH) resulting from our achievement of FDA marketing authorization and European CE Mark for T2Dx and T2Candida during the quarter, $0.3 million of increased facilities-related costs and $0.2 million of increased lab expenses to support product development. Partially offsetting these increases are decreased travel and site expenses of $0.3 million resulting from the completion of pivotal clinical trial for T2Dx and T2Candida in the first half of 2014.

Selling, general and administrative expenses

Selling, general and administrative expenses were $3.0 million for the three months ended September 30, 2014, compared to $1.3 million for the three months ended September 30, 2013. The increase of $1.7 million was due primarily to increased payroll and related expenses of $1.0 million, including $0.4 million of stock compensation expense, as we hired new executive, sales and administrative employees, increased marketing program expenses of $0.2 million, related to attendance at trade shows, website redesign and collateral, increased legal and consulting related expenses of $0.3 million and $0.2 million of increased other public company expenditures (related to insurance and board of directors fees).

Interest expense, net

Interest expense, net, increased for the three months ended September 30, 2014, compared to the three months ended September 30, 2013, due to higher borrowing levels on our notes payable and the write-off of deferred financing costs in connection with the repayment of outstanding

borrowings from a lender.

Table of Contents

Results of Operations for the Nine Months Ended September 30, 2014 and 2013

	Nine Months Ended September 30,		
	2014	2013	Change
	(in thousands)		
Research and grant revenue	$	$ 211	$ (211)
Operating expenses:			
Research and development	14,572	10,646	3,926
Selling, general and administrative	7,271	3,618	3,653
Total operating expenses	21,843	14,264	7,579
Loss from operations	(21,843)	(14,053)	(7,790)
Interest expense, net	(471)	(310)	(161)
Other income (expense), net	(1)	125	(126)
Net loss	$ (22,315)	$ (14,238)	$ (8,077)

Revenue

We recorded $0.2 million of research and grant revenue for the nine months ended September 30, 2013, which primarily consisted of revenue related to feasibility studies and co-development efforts with three companies.

Research and development expenses

Research and development expenses were $14.6 million for the nine months ended September 30, 2014, compared to $10.6 million for the nine months ended September 30, 2013, an increase of $3.9 million. The increase was primarily due to increased payroll and payroll related expenses of $1.7 million, including $0.3 million of stock compensation expense, as we hired new employees and expanded our use of contractors and temporary help, increased travel and site expenses of $0.6 million related to the pivotal clinical trial for T2Dx and T2Candida, $0.6 million of increased lab expenses, $0.5 million of increased facilities-related expenses, increased licensing fees of $0.3 million resulting from milestone payments that became due pursuant to our license arrangement with MGH as a result of our achievement of FDA marketing authorization and European CE Mark for T2Dx and T2Candida during the third quarter, and $0.2 million of increased consulting expense incurred to support product development.

Selling, general and administrative expenses

Selling, general and administrative expenses were $7.3 million for the nine months ended September 30, 2014, compared to $3.6 million for the nine months ended September 30, 2013. The increase of $3.7 million was due primarily to increased payroll and related expenses of $2.4 million, including $0.8 million of stock compensation expense, as we hired new executive and administrative employees, increased marketing program expenses of $0.5 million (related to exhibits at tradeshows, travel and collateral), increased consulting related expenses of $0.3 million, increased legal expenses of $0.2 million related to corporate and intellectual property matters, $0.2 million of increased other public company expenditures (related to insurance and board of directors fees) and $0.1 million of increased facilities-related expenses.

Interest expense, net

Interest expense, net, increased for the nine months ended September 30, 2014, compared to the nine months ended September 30, 2013, due to higher borrowing levels on our notes payable and the write-off of deferred financing costs in connection with the repayment of outstanding borrowings from a lender.

Other income (expense), net

Other income (expense), net, for the nine months ended September 30, 2014 declined when compared with the nine months ended September 30, 2013, due to a decrease in income related to the change in the fair value of the liability for warrants to purchase redeemable securities.

Table of Contents

Liquidity and Capital Resources

We have incurred losses and cumulative negative cash flows from operations since our inception, and as of September 30, 2014, we had an accumulated deficit of $94.5 million. We anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and selling, general and administrative expenses will continue to increase and, as a result, we may need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

Since our inception through September 30, 2014, we have raised an aggregate of $169.8 million to fund our operations, of which $93.4 million was from the sale of preferred stock, $58.0 million was from the issuance of 5,980,000 of common stock upon completion of our IPO on August 12, 2014, and $18.1 million and $0.3 million were from the issuance of debt and common stock from stock incentive awards, respectively. As of September 30, 2014, we had cash and cash equivalents of $75.6 million. Currently, our funds are primarily held in interest bearing deposit accounts and in money market funds invested consistent with our investment policy.

On July 11, 2014, the Company entered into a Note Agreement with two lenders to borrow up to $30.0 million for operations. The Note Agreement allows the Company to borrow amounts in two tranches, up to $20.0 million (drawn in amounts not less than $10.0 million upon closing and the remainder drawn in amounts not less than $5.0 million draws) by December 31, 2014 for tranche A and up to $10.0 million by June 30, 2015 for tranche B. Borrowings under tranche B are only available to the Company if both of the following conditions are met by June 30, 2015: (a) the Company receives Section 510(k) clearance from the FDA on the Company s T2Dx and T2Candida products and (b) the Company completes a public or private stock offering, equity raise or strategic partner arrangement resulting in the receipt of at least $30.0 million in net proceeds by the Company. As the Company received FDA approval in September 2014 and the Company closed its initial public offering in August 2014, the borrowings under tranche B are now available as both of the required conditions have been met. The Company received proceeds of $9.8 million under tranche A, net of deferred financing costs. To date, the Company has not drawn the remaining tranche A and tranche B available borrowings. In connection with the closing of the Note Agreement, the Company repaid all amounts outstanding under previously existing borrowing arrangement with a lender, totaling approximately $2.9 million, as of July 11, 2014.

On July 11, 2014, the Company entered into a lease amendment to expand facilities at the Company s headquarters in Lexington, MA. The term of the lease amendment ends concurrently with the original lease entered into in August 2010 and will increase the monthly base rent by approximately $39,000 per month through December 2015. The Company retains the option to extend the lease for one additional term of two years.

We believe that our existing cash and cash equivalents, and additional liquidity of up to $20.0 million obtained from the July 11, 2014 Note Agreement, will be sufficient to meet our anticipated cash requirements for at least the next 18 months.

Table of Contents

Cash flows

The following is a summary of cash flows for each of the periods set forth below:

	Nine Months Ended September 30,	
	2014	2013
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (19,699)	$ (13,475)
Investing activities	(1,039)	(370)
Financing activities	66,129	39,355
Net (decrease) increase in cash and cash equivalents	$ 45,391	$ 25,510

Net cash used in operating activities

Net cash used in operating activities was approximately $19.7 million for the nine months ended September 30, 2014, and consisted primarily of a net loss of $22.3 million adjusted for non-cash items including depreciation and amortization expense of $0.5 million, stock-based compensation expense of $1.1 million, non-cash interest expense of $0.1 million and a net change in operating assets and liabilities (source) of $1.0 million.

Net cash used in operating activities was approximately $13.5 million for the nine months ended September 30, 2013, and consisted primarily of a net loss of $14.2 million adjusted for non-cash items including depreciation and amortization expense of $0.4 million, stock-based compensation expense of $0.3 million, a decrease in the fair value of warrants of $0.1 million and a net change in operating assets and liabilities (source) of $0.1 million.

Net cash used in financing activities

Net cash used in investing activities was approximately $1.0 million for the nine months ended September 30, 2014, and consisted of $1.0 million of purchases of laboratory equipment, leasehold improvements and computer software.

Net cash used in investing activities was approximately $0.4 million for the nine months ended September 30, 2013, and consisted of $0.5 million of purchases of laboratory equipment, partially offset by $0.1 million of decrease in restricted cash accounts related to a refund of a security deposit due under an operating lease agreement.

Net cash provided by financing activities

Net cash provided by financing activities was approximately $66.1 million for the nine months ended September 30, 2014, and consisted of $60.1 million of proceeds from the issuance of common stock from our IPO in August 2014, net of offering costs paid, $5.8 million of proceeds, net of principal repayments and the payment of deferred financing costs, from notes payable and $0.2 million of proceeds from the exercise of stock options. At September 30, 2014, there were $2.1 million of offering costs from our IPO that have been incurred, but are unpaid.

Net cash provided by financing activities was approximately $39.4 million for the nine months ended September 30, 2013, and primarily related to the sale of 6.9 million shares of our series E preferred stock for net proceeds of $39.8 million, partially offset by repayments of notes payable of $0.5 million.

Contractual Obligations and Commitments

Refer to Liquidity and Capital Resources for discussion of material changes to contractual obligations and commitments from those described under Management s Discussion and Analysis of Financial Condition and Results of Operations in the Registration Statement on Form S-1 filed on August 6, 2014. There were no material changes to our contractual obligations and commitments subsequent to September 30, 2014.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under Securities and Exchange Commission, or SEC, rules.

Table of Contents

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risk related to changes in interest rates. As of September 30, 2014, we had cash and cash equivalents of $75.6 million held primarily in an interest bearing deposit account and a money market fund account consisting of U.S. government-backed securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate one percent change in interest rates would not have a material effect on the fair market value of our portfolio. We are also subject to interest rate risk from the Note Agreement, which bears interest at an annual rate equal to the one-month LIBOR plus 7.05%, or 7.21% at September 30, 2014.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

Management of the Company, with the participation of the Chief Executive Officer and the Chief Financial Officer, evaluated the effectiveness of the design and operation of the Company s disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) as of September 30, 2014. The Company s disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported on a timely basis and that such information is accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding disclosure. Based upon this evaluation, the Chief Executive Officer and the Chief Financial Officer have concluded that the Company s disclosure controls and procedures were effective as of September 30, 2014.

(b) Changes in Internal Control over Financial Reporting

There have been no material changes to the Company s internal control over financial reporting during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company s internal control over financial reporting.

Table of Contents

PART II.

OTHER INFORMATION

Item 1. Legal Proceedings

We may be from time to time subject to various claims and legal actions during the ordinary course of our business. There are currently no claims or legal actions, individually or in the aggregate, that would have a material adverse effect on our results of operations or financial condition.

Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Risk Factors in our Registration Statement on Form S-1 filed with the Securities and Exchange Commission, or SEC, on August 6, 2014, which could materially affect our business, financial condition or future results. There have been no material changes from the risk factors previously disclosed in our Registration Statement on Form S-1.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Set forth below is information regarding equity securities sold or issued by us during the nine months ended September 30, 2014 that were not registered under the Securities Act at the time of sale or issuance. Also included is the consideration, if any, received by us for such equity securities and information relating to the section of the Securities Act, or rule of the SEC, under which exemption from registration was claimed.

Between January 1, 2014 and September 30, 2014, we granted options to purchase an aggregate of 672,972 shares of common stock, with a weighted-average exercise price of $11.98 per share, to our employees and directors pursuant to our 2006 and 2014 Stock Incentive Plans. Options granted generally vest over four years from the date of grant. Between January 1, 2014 and September 30, 2014, we issued an aggregate of 63,602 shares of common stock upon the exercise of options for aggregate consideration of approximately $150,000 and options to purchase 84,018 shares had been cancelled. We filed a registration statement on Form S-8 under the Securities Act to register all shares of our common stock subject to outstanding options and other awards issuable pursuant to our equity compensation plans.

The stock options and the common stock issuable upon the exercise of such options as described in this section were issued pursuant to written compensatory plans or arrangements with our employees, directors and consultants, in reliance on the exemption provided by Rule 701 promulgated under the Securities Act. All recipients either received adequate information regarding our Company or had access, through employer or other relationships, to such information.

Use of Proceeds

Use of Proceeds from the Sale of Unregistered Securities

Proceeds of approximately $150,000 received from the issuance of common stock upon the exercise of options were principally used to fund operations.

Use of Proceeds from the Sale of Registered Securities

On August 6, 2014, the SEC declared effective our Registration Statement on Form S-1 (File No. 333-197920), as amended, or Registration Statement, filed in connection with the initial public offering of our common stock. Pursuant to the Registration Statement, we registered the offer and sale of 5,200,000 shares of common stock with an aggregate offering price of approximately $57.2 million. Goldman Sachs & Co and Morgan Stanley acted as joint book-running managers for the offering, Leerink Partners and Janney Montgomery Scott acted as co-managers. On August 8, 2014, the underwriters exercised in full their option to purchase additional shares pursuant to the underwriting agreement. On August 12, 2014, we closed the initial public offering, including 780,000 of additional shares related to the option to purchase additional shares pursuant to the underwriting agreement, and sold a total of 5,980,000 shares at a price to the public of $11.00 per share for net proceeds of $58.0 million, which is comprised of gross proceeds for $65.8 million, offset by underwriting discounts and commissions of $4.6 million and estimated offering expenses of $3.2 million. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

Table of Contents

The net proceeds of approximately $58.0 million from our initial public offering have been invested in accordance with the Company s investment policy. From the date of the closing of our initial public offering through September 30, 2014, we have not fully used cash on hand that was available prior to the closing of the initial public offering. There has been no material change in the expected use of the net proceeds from our initial public offering as described in our final prospectus, dated August 6, 2014, filed with the SEC pursuant to Rule 424(b) relating to our Registration Statement.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Table of Contents

Item 6. Exhibits, Financial Statement Schedules

Exhibit Number	Exhibit Description
31.1*	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.1*	The following financial statements from the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, formatted in XBRL: (i) Balance Sheets (unaudited), (ii) Statements of Operations and Comprehensive Loss (unaudited), (iii) Statements of Cash Flows (unaudited), and (v) Notes of Consolidated Financial Statements.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

	T2 Biosystems, Inc.	
Date: November 5, 2014	By:	/s/ John McDonough John McDonough President and Chief Executive Officer
	T2 Bioystems, Inc.	
Date: November 5, 2014	By:	/s/ Marc R. Jones Marc R. Jones Chief Financial Officer